

REMARKS

I. Status of the Claims and Amendments

Claims 1-29 were pending. Claims 14-25, 28, and 29 were withdrawn by the Office as being drawn to a non-elected invention. Office Action, page 2. Applicants have canceled claims 14-25, 28, and 29 without prejudice or disclaimer of that subject matter and they reserve their right to file a divisional application directed to the non-elected subject matter. Applicants have also canceled claims 9-13, 26, and 27 also without in anyway disclaiming the subject matter of those claims. They reserve their right to file one or more continuation application based on canceled claims 9-13, 26, and 27. New claims 30-33 have been added.

Claim 1 has been amended to clarify that the endophyte is a "biologically pure culture of an endophyte." Support for this amendment is found throughout the specification and original, for example, in claim 7 and in the disclosure at page 8, lines 9-22. Applicants have also amended the preambles of claims 2-8 to reflect the amendment to claim 1. Accordingly, those amendments are supported in the same location.

The language of claim 1 has also been amended to clarify that the endophyte is "characterised in that when the endophyte is combined with a host grass, the endophyte does not produce alkaloid compounds at levels associated with toxicosis in animals . . ." Applicants respectfully submit that this amendment merely clarifies what was already recited in the claim. Accordingly, support is found in original claim 1 and the amendment does not alter the claim scope. Support for the amendment is also found in the abstract of the specification, among other locations.

In addition, Applicants have amended claim 1 to recite that the endophyte is "characterised in that when the endophyte is combined with a host grass, the endophyte produces at least two clavine alkaloids selected from the group consisting of: agroclavine; setoclavine; isosetoclavine; and combinations thereof." In this case, too, Applicants respectfully submit that this amendment merely clarifies what was already recited in the claim and does not alter its scope. Support is found in original claim 1 and in the abstract of the specification, among other locations.

The amendments to claims 2-5 bring the language of those dependent claims into line with the amendments to claim 1. Accordingly, support for those amendment is found at least in original claims 1-5 and in the abstract of the specification. Dependent claim 6 incorporates the language canceled from claim 1. Support is therefore found at least in original claim 1. Claim 7 has been amended to depend from claim 6 and to recite the subject matter that was previously found in claim 6. Thus, the amendments to claim 7 are supported at least in original claim 6. The amendments to claim 8 revise its dependency (from claim 7 to claim 1) and clarify that the culture is a biologically pure culture. Support for the amendments to claim 8 is found at least in original claim 7, and in the same locations as for claim 1, from which it now depends.

New claims 30 and 32 find support throughout the specification and original claims; for example, original claim 7. New claim 32 also finds explicit support on page 14, lines 22-26, and in Table 2 on page 15. New claims 31 and 33 are supported at least by original claim 8, and in the specification on page 5, line 29.

These amendments do not add any new matter.

II. 35 U.S.C. § 101

The Office rejects claims 1-13 and 26-27 under 35 U.S.C. § 101 as drawn to nonstatutory subject matter because, according to the Office, the claim reads on an organism as found in nature. Office Action, page 2. Applicants have amended the claims as the Office suggests. They therefore respectfully request that the Office withdraw the rejection.

III. 35 U.S.C. § 112, Second Paragraph

Claims 1-7, 9-13, and 26-27 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for various reasons. Office Action, page 3.

According to the Office, claims 1 and 7 are indefinite in their recitation of a process step in a product claim. *Id.* Applicants have deleted the process language from claim and amended claim 7 to depend indirectly from claim 1.

It is also the Office's position that "the properties recited are in terms of and dependent upon the growth of the [endophyte] on a host grass and are not descriptive of the properties of the strains intended." *Id.* Applicants have amended the claim language so that it is more descriptive of properties of the endophyte. Although those properties only manifest upon culture of the endophyte in its host grass, Applicants respectfully submit that they nevertheless serve to describe properties of the endophytes. "If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. § 112, second paragraph, would be appropriate." M.P.E.P. § 2173.02. In this case, however, although the person of ordinary skill would need to grow the endophyte culture on a host grass to determine

whether it was within the metes and bounds of the claim, once that test was undertaken, it would be clear whether the endophyte was within the scope of the claims. Thus, Applicants respectfully submit that the claims are reasonably precise, which is all that is required. *Id.* For the same reasons, Applicants respectfully submit that claims 2-6 do further limit the subject matter of claim 1.

The Office objects to claims 4-6, 10-13, and 26-27 under 37 C.F.R. § 1.75(c) as being in improper multiple dependent form. *Id.* Applicants have amended the claims so that they are no longer multiply dependent.

IV. 35 U.S.C. § 112, first paragraph

The Office rejects 1-13 and 26-27 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to enable the skilled artisan to practice the claimed invention. *Id.* The Office asks that Applicants clarify whether the recited strains have been deposited so that the starting material will be available to the public. *Id.* at 4.

Applicants enclose as an attachment to this response copies of the deposit certificates for each of the recited strains. As indicated on the deposit certificates, each endophyte was deposited with the Australian Government Analytical Laboratories (AGAL), The New South Wales Regional Laboratory, 1, Suakin Street Pymble NSW 2073, Australia, on October 2, 2002, under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (see title of form). All restrictions on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

The original deposit was specifically identified in the application as-filed on page 4, lines 24-28 and on page 8, lines 10-17, among other places. However, Applicants have amended the specification on page 8 to clearly indicate the relationship between each name and deposit number, to provide the address of the international depository authority, and to list the date of the deposit. The strains are described in detail in the specification in terms of the chemicals they produce when cultivated (e.g., Table 1) and their genotype with respect to microsatellite mapping for alleles B10 and B11 (Table 2.) Accordingly, Applicants respectfully request that the Office withdraw this rejection.

V. Rejections Under 35 U.S.C. §§ 102/103(a)

A. Waller

Claims 1-13 and 26-27 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly unpatentable over Waller et al., "Tall Fescues with Novel Endophytes in Tennessee." In Proc 4th Int'l Neotyphodium/Grass Interactions Symp (2000) ("Waller"). Office action, page 5.

The Office characterizes the claims as drawn to "*Neotyphodium coenophialum* strains which are non-toxic for animals in conjunction with grasses." *Id.* It points to the strains described in the Results, and Tables I and II of Waller and notes that those strains are non-toxic for grazing animals. *Id.* It is therefore the Office's position that the claimed strains are either the same as those taught by Waller, *id.*, or else their differences are "so slight that the referenced microorganisms are likely to inherently possess the same characteristics," *id.* at 6.

Applicants respectfully traverse this rejection. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to

reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. 2112.IV (quoting *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). Further, "[a] claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possibly present." *Akamai Technologies, Inc. v. Cable & Wireless Internet Serv., Inc.*, 344 F.3d 1186, 1192, 68 U.S.P.Q.2d 1186, 1190 (Fed. Cir. 2003).

As an initial matter, Applicants note that, despite the Office's characterization of the claims as drawn to any *N. coenophialum* strain that is non-toxic for animals in conjunction with grasses, the claims considered by the Office included additional elements. In addition, the Office's inherency argument fails to address the evidence presented in the specification that indicates that not all strains of *N. coenophialum* that are non-toxic to grazing animals have the same properties. Specifically, Table 1 on page 13 and Table 2 on page 15 summarizes data for various of the claimed strains compared to strains AR501 and AR542. Table 1 of the current application shows that strain AR542 does not produce detectable levels of the clavine alkaloids and strain AR501 produces only trace or low levels of clavine alkaloids. In addition, as shown in Table 2 on page 15, each of AR501 and AR542 has only two alleles at the B10 locus. U.S. Patent No. 6,111,170, previously considered by the Office, describes these strains in more detail and notes that AR501 belongs to the same group as strain AR502, at least as determined by allele analysis. U.S. Patent No. 6,111,179, col. 5, Table 2. Thus, a non-toxic *N. coenophialum* endophyte is not necessarily a *N. coenophialum* endophyte as claimed.

Waller describes studies with strains AR502 and AR542. Those strains, however, do not possess either the same functional properties (production of at least two clavine alkaloids selected from the group consisting of: agroclavine; setoclavine; isosetoclavine, as disclosed for the claimed strains, or genotypic properties, such as at the presence of three B10 alleles. Accordingly, those strains do not anticipate the claimed strains.

Further, AR502 and AR542 do not render the claimed strains obvious, contrary to the Office's assertion. "Rejections on obviousness cannot be sustained by mere conclusory statement; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __, 82 USPQ2d 1385, 1396 (2007). In this case, the specification provides direct evidence that the claimed strains have unique properties. In particular, as summarized in the specification on page 7, lines 11-17, the claimed endophytes produce only low levels of the alkaloid ergovaline (and so they do not cause toxicosis in grazing animals) *but still produce at least two clavine alkaloids*. The production of the clavine alkaloids is important to the symbiote's ability to resist abiotic stresses, such as water deficit, and to resist pests.

For the reasons given, the claims are neither anticipated by nor obvious variations of the strains taught by Waller. Accordingly, Applicants respectfully request that the Office withdraw these rejections.

B. Smith

Claims 1-13 and 26-27 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly unpatentable

over Smith et al., "Crop and Soil Environmental Sciences" Pub 418-050 (2002) ("Smith"). Office action, page 6.

The Office again characterizes the claims as drawn to "*Neotyphodium coenophialum* strains which are non-toxic for animals in conjunction with grasses." *Id.* It points to the last page at column 2 for Smith's teaching of a non-toxic endophyte "MaxQ". *Id.*

Smith's MaxQ™ strain is referenced in the specification on page 2, lines 2-3. It was described in U.S. Patent No. 6,111,170 (of record) and by Bouton, 2000 (of record) and Bouton, 2002 (of record). As taught in Bouton, 2000, page 167 (just before table 5), "MaxQ™" is the trade name under which AR542 is marketed. Applicants have addressed the reasons why strain AR542 neither anticipates nor renders obvious the claimed strains *supra* in part V.B. Therefore, they respectfully request that the Office withdraw this rejection.

C. Matthews

Claims 1-13 and 26-27 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly unpatentable over Matthews et al., J. Anim. Sci. 83:1179-85 (2005) ("Matthews"). Office action, page 7.

Applicants respectfully traverse this rejection. Matthews is a printed, non-patent publication that published in 2005. The instant application is the National Stage of International Application PCT/NZ03/00219, filed Sept. 26, 2003. Accordingly, Matthews is not available as a reference under any section of 35 U.S.C. § 102. Applicants respectfully request that the Office withdraw this rejection.

D. Smith

Claims 1-13 and 26-27 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly unpatentable over Bouton et al., *Agronomy J.* 94:567-74 (2002) ("Bouton"). Office action, page 7. The Office points to the teachings of Bouton in Table 1 in rejecting the claims. *Id.*

Applicants respectfully traverse this rejection for the reasons discussed in detail *supra* in part V.B. In particular, they note that Bouton teaches strains AR502, AR510, AR542, AR572, and AR577. Those strains are described in detail in U.S. Patent No. 6,111,170 (of record). As taught in the '170 patent, strains AR502, AR510, AR572, and AR577 belong to one group based on their microsatellite patterns, while AR542 belongs to another group. '170 patent, col. 5, Table 2. Neither group, however, has the same microsatellite pattern as the claimed strains, at least because the strains in the '170 patent all have only two alleles at the B10 locus. Therefore, those strains do not possess the same genetic properties as the claimed strains. Also, there is no evidence that the strains in Bouton produce at least two clavine alkaloids selected from the group consisting of: agroclavine; setoclavine; iso-setoclavine. To the contrary, the evidence in the specification suggest they do not produce detectable levels of those clavine alkaloids.

The endophyte strains described in Bouton have different genetic properties and there is no evidence that they possess all of the same functional properties as the claimed strains. That reference, therefore does not teach or suggest the claimed strains. Applicants respectfully request that the Office withdraw the rejection.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 21, 2008

By: 
Jessica H. Roark
Reg. No. 54,869

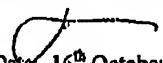
BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO : AgResearch Limited
Grasslands Research Centre
Tennent Drive
Private Bag 11008
Palmerston North
New Zealand

ATTENTION : Wayne Simpson
NAMES AND ADDRESS
[OF DEPOSITOR]

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
Issued pursuant to Rule 7.1 by the
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I IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: <i>Neotyphodium coenophialum AR512</i>	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: <i>NM02/31935</i>
II SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: <input type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable)	
III RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 2 nd October, 2002 (date of the original deposit) ¹	
IV RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depository Authority on (date of original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
V INTERNATIONAL DEPOSITORY AUTHORITY	
Name: AUSTRALIAN GOVERNMENT ANALYTICAL LABORATORIES Address: PO BOX 385 PYMBLE NSW 2073 AUSTRALIA Phone: (02) 9449 0111 Facsimile: (02) 9449 1653	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorised official(s)  Date: 16 th October, 2002

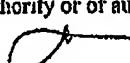
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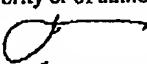
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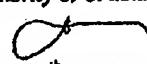
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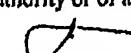
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Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:
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<i>Neotyphodium coenophialum AR522</i>	NM02/31940

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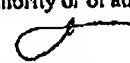
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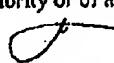
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Name: AUSTRALIAN GOVERNMENT ANALYTICAL LABORATORIES Address: PO BOX 385 PYMBLE NSW 2073 AUSTRALIA Phone: (02) 9449 0111 Facsimile: (02) 9449 1653	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorised official(s)  Date: 16 th October, 2002

¹ Where Rule 6.4(d) applies, such date is the date on which the status of International Depository Authority was acquired.

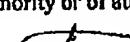
BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO : AgResearch Limited
Grasslands Research Centre
Te Rauhī Drive
Private Bag 11008
Palmerston North
New Zealand

ATTENTION : Wayne Simpson
NAME AND ADDRESS
OF DEPOSITOR

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITORY AUTHORITY
identified at the bottom of this page

I IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:
<i>Neotyphodium coenophialum ARS25</i>	NM02/31942
II SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: <input type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable)	
III RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 2 nd October, 2002 (date of the original deposit)	
IV RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depository Authority on (date of original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
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Name: AUSTRALIAN GOVERNMENT ANALYTICAL LABORATORIES Address: PO BOX 385 PYMBLB NSW 2073 AUSTRALIA Phone: (02) 9449 0111 Facsimile: (02) 9449 1653	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorised official(s)  Date: 16 th October, 2002

1 Where Rule 6.4(d) applies, such date is the date on which the status of International Depository Authority was acquired.

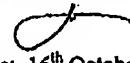
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I IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:
<i>Neotyphodium coenophialum</i> AR535	NM02/31943
II SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: <input type="checkbox"/> a scientific description <input checked="" type="checkbox"/> a proposed taxonomic designation (Mark with a cross where applicable)	
III RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 2 nd October, 2002 (date of the original deposit) ¹	
IV RECEIPT OF REQUEST FOR CONVERSION	
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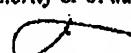
¹ Where Rule 6.4(d) applies, such date is the date on which the status of International Depository Authority was acquired.

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
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NM02/31944	
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